A method for producing a polypeptide comprising:

(a) providing a microorganism in a culture containing a DNA encoding a fusion polypeptide comprising at least one epitope of a 16 (±4) kDa antigen [and/or] or 30 (±4) kDa antigen or combinations thereof of *Sarcocystis neurona* and an additional [a] polypeptide that facilitates isolation of the fusion polypeptide;

(b) culturing the microorganism in a culture to produce the fusion polypeptide; and

(c) isolating the fusion polypeptide.

REMARKS

Claims 4 to 9, 13 to 17, 23 to 28, 45, 46, 49 and 50 are pending. No claims are allowed.

Claims 1 to 50 were subject to a restriction requirement. Applicants affirm the election of Claims 4 to 9, 3 to 17, 23 to 28, 45, 46, 49 and 50 in Group II. The election is without traverse.

Claims 4 to 9, 13 to 17, 45-46 and 49-50 were rejected under 35 USC 112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention". The Applicants request reconsideration in view of the following remarks. The claims are to an antigen vaccine.

The vaccine of the present invention can provide protection by producing antibodies *in vivo* which interfere with the function of surface proteins of the *Sarcocystis neurona* enabling the organism to enter into the nervous system or CSF. Liang et al (1998), cited in the Office Action, recognizes that the one of the proteins, Sn16, might be important in a vaccine as a surface protein, but in no way suggests using recombinant antigens for this purpose. The "Sn30" surface antigen is stated on page 1836, in the beginning paragraph, to not produce inhibition by sera containing antibodies; however, this is incorrect as Applicants have shown in the specification.

The claimed vaccine thus does not prevent the *Sarcocystis neurona* from infecting the equids, since in fact the parasite is epidemic in horses in the United States. What the vaccine can accomplish is that it prevents the horse from acquiring the disease in the CSF or nervous system as noted by Liang et al. The reason that some horses do not exhibit the disease although they are infected may be that they have developed antibodies in sera which interfere with the surface antigens of the parasite; however, this is unknown and unproven.

Killed cells of *Sarcocystis neurona* are being developed and is in trials by Fort Dodge (Iowa). The premise of this vaccine is to develop antibodies to proteins in the *Sarcocystis neurona* in serum in the equid. The problem with this whole cell vaccine is that

there is no way to tell whether or not the animal has a natural immunity or has been vaccinated, because of the broad mixture of proteins from the whole cells. The recombinant vaccine of the present invention solves this problem.

Finally, Liang et al is merely an invitation to experiment. The reference does not suggest that a recombinant vaccine is to be produced.

There is no "trial and error" involved in the present invention. The present invention can easily be practiced by one skilled in the art using Applicants' disclosure. The Fort Dodge vaccine provides a precedent for the type of vaccine claimed.

Claims 23 to 28 relate to producing fusion proteins. The application enables *E. coli* and other microorganisms (page 16 and Claim 6) for producing the fusion protein. In any event, the production of fusion proteins in general is well known to those skilled in the art. What is novel about the invention is the 16 (±4) and/or 30 Kd (±4) recombinant proteins which are used to practice the present invention. The isolated proteins are used for vaccines and for kits. Reconsideration is requested.

Claim 4 was rejected under 35 USC 102(b) over Liang et al (1998). Claim 4 has been amended to cover only the "recombinant" antigen(s) as in the remaining claims. Reconsideration of this rejection is requested.

It is now believed that Claims 4 to 9, 13 to 17, 23 to 28, 45, 46, 49 and 50 are in condition for allowance. Notice of allowance is requested.

Respectfully,

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